

in paragraph (d)(1) of this section) whose entitlement to regular military health services system coverage ended on or after August 2, 1994, but prior to the CHCBP implementation on October 1, 1994.

(2) Enrollment in the U.S. VIP program may continue up to October 1, 1994. Policies written prior to October 1, 1994, will remain in effect until the end of the policy life.

(3) On or after the October 1, 1994, implementation of the Continued Health Care Benefit Program, beneficiaries who enrolled in the U.S. VIP program prior to October 1, 1994, may elect to cancel their U.S. VIP policy and enroll in the CHCBP.

(4) With the exception of persons enrolled in the U.S. VIP program who may convert to the CHCBP, individuals who lost their entitlement to regular military health services system coverage prior to August 2, 1994, are not eligible for the CHCBP.

(s) *Procedures.* The Director, OCHAMPUS, may establish other rules and procedures for the administration of the Continued Health Care Benefit Program.

[59 FR 49818, Sept. 30, 1994, as amended at 62 FR 35097, June 30, 1997; 64 FR 46141, Aug. 24, 1999; 69 FR 51569, Aug. 20, 2004]

§ 199.21 Pharmacy benefits program.

(a) General—(1) *Statutory authority.* Title 10, U.S. Code, Section 1074g requires that the Department of Defense establish an effective, efficient, integrated pharmacy benefits program for the Military Health System. This law is independent of a number of sections of Title 10 and other laws that affect the benefits, rules, and procedures of TRICARE, resulting in changes to the rules otherwise applicable to TRICARE Prime, Standard, and Extra.

(2) *Pharmacy benefits program.* The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Its geographical applicability is all 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In addition, if authorized by the Assistant Secretary of Defense (Health Affairs), the TRICARE program may be implemented in areas

outside the 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In such case, the Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the pharmacy benefits program rules as may be appropriate to the areas involved.

(3) *Uniform formulary.* The pharmacy benefits program features a uniform formulary of pharmaceutical agents as defined in § 199.2.

(i) The uniform formulary will assure the availability of pharmaceutical agents in the complete range of therapeutic classes authorized as basic program benefits.

(ii) As required by 10 U.S.C. 1074g(a)(2) and implemented under the procedures established by paragraphs (e) and (f) of this section, pharmaceutical agents in each therapeutic class are selected for inclusion on the uniform formulary based upon the relative clinical effectiveness and cost effectiveness of the agents in such class. If a pharmaceutical agent in a therapeutic class is determined by the Department of Defense Pharmacy and Therapeutics Committee not to have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other pharmaceutical agents included on the uniform formulary, the Committee may recommend it be classified as a non-formulary agent. In addition, if the evaluation by the Pharmacy and Therapeutics Committee concludes that a pharmaceutical agent in a therapeutic class is not cost effective relative to other pharmaceutical agents in that therapeutic class, considering costs, safety, effectiveness, and clinical outcomes, the Committee may recommend it be classified as a non-formulary agent.

(iii) Pharmaceutical agents which are used exclusively in medical treatments or procedures that are expressly excluded from the TRICARE benefit by statute or regulation will not be considered for inclusion on the uniform formulary. Excluded pharmaceutical agents shall not be available as non-formulary agents, nor will they be cost-shared under the TRICARE pharmacy benefits program.

(b) *Definitions.* For most definitions applicable to the provisions of this section, refer to §199.2. The following definitions apply only to this section:

(1) *Clinically necessary.* Also referred to as clinical necessity. Sufficient evidence submitted by a beneficiary or provider on behalf of the beneficiary that establishes that one or more of the following conditions exist: The use of formulary pharmaceutical agents is contraindicated; the patient experiences significant adverse effects from formulary pharmaceutical agents in the therapeutic class, or is likely to experience significant adverse effects from formulary pharmaceutical agents in the therapeutic class; formulary pharmaceutical agents result in therapeutic failure, or the formulary pharmaceutical agent is likely to result in therapeutic failure; the patient previously responded to a non-formulary pharmaceutical agent and changing to a formulary pharmaceutical agent would incur an unacceptable clinical risk; or there is no alternative pharmaceutical agent on the formulary.

(2) *Therapeutic class.* A group of pharmaceutical agents that are similar in chemical structure, pharmacological effect, and/or clinical use.

(c) *Department of Defense Pharmacy and Therapeutics Committee—(1) Purpose.* The Department of Defense Pharmacy and Therapeutics Committee is established by 10 U.S.C. 1074g to assure that the selection of pharmaceutical agents for the uniform formulary is based on broadly representative professional expertise concerning relative clinical and cost effectiveness of pharmaceutical agents and accomplishes an effective, efficient, integrated pharmacy benefits program.

(2) *Composition.* As required by 10 U.S.C. 1074g(b), the committee includes representatives of pharmacies of the uniformed services facilities and representatives of providers in facilities of the uniformed services. Committee members will have expertise in treating the medical needs of the populations served through such entities and in the range of pharmaceutical and biological medicines available for treating such populations.

(3) *Executive Council.* The Pharmacy and Therapeutics Committee may have

an Executive Council, composed of those voting and non-voting members of the Committee who are military or civilian employees of the Department of Defense. The function of the Executive Council is to review and analyze issues relating to the operation of the uniform formulary, including issues of an inherently governmental nature, procurement sensitive information, and matters affecting military readiness. The Executive Council presents information to the Pharmacy and Therapeutics Committee, but is not authorized to act for the Committee.

(d) *Uniform Formulary Beneficiary Advisory Panel.* As required by 10 U.S.C. 1074g(c), a Uniform Formulary Beneficiary Advisory Panel reviews and comments on the development of the uniform formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries, contractors responsible for the TRICARE retail pharmacy program, contractors responsible for the TRICARE mail-order pharmacy program, and TRICARE network providers. The panel will meet after each Pharmacy and Therapeutics Committee quarterly meeting. The Panel's comments will be submitted to the Director, TRICARE Management Activity. The Director will consider the comments before implementing the uniform formulary or any recommendations for change made by the Pharmacy and Therapeutics Committee. The Panel will function in accordance with the Federated Advisory Committee Act (5 U.S.C. App. 2).

(e) *Determinations regarding relative clinical and cost effectiveness for the selection of pharmaceutical agents for the uniform formulary—(1) Clinical effectiveness.* (i) It is presumed that pharmaceutical agents in a therapeutic class are clinically effective and should be included on the uniform formulary unless the Pharmacy and Therapeutics Committee finds by a majority vote that a pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over the other pharmaceutical

agents included on the uniform formulary in that therapeutic class. This determination is based on the collective professional judgment of the DoD Pharmacy and Therapeutics Committee and consideration of pertinent information from a variety of sources determined by the Committee to be relevant and reliable. The DoD Pharmacy and Therapeutics Committee has discretion based on its collective professional judgment in determining what sources should be reviewed or relied upon in evaluating the clinical effectiveness of a pharmaceutical agent in a therapeutic class.

(ii) Sources of information may include but are not limited to:

- (A) Medical and pharmaceutical textbooks and reference books;
- (B) Clinical literature;
- (C) U.S. Food and Drug Administration determinations and information;
- (D) Information from pharmaceutical companies;
- (E) Clinical practice guidelines, and
- (F) Expert opinion.

(iii) The DoD Pharmacy and Therapeutics Committee will evaluate the relative clinical effectiveness of pharmaceutical agents within a therapeutic class by considering information about their safety, effectiveness, and clinical outcome.

(iv) Information considered by the Committee may include but is not limited to:

- (A) U.S. Food and Drug Administration approved and other studied indications;
- (B) Pharmacology;
- (C) Pharmacokinetics;
- (D) Contraindications;
- (E) Warnings/precautions;
- (F) Incidence and severity of adverse effects;
- (G) Drug to drug, drug to food, and drug to disease interactions;
- (H) Availability, dosing, and method of administration;
- (I) Epidemiology and relevant risk factors for diseases/conditions in which the pharmaceutical agents are used;
- (J) Concomitant therapies;
- (K) Results of safety and efficacy studies;
- (L) Results of effectiveness/clinical outcomes studies, and
- (M) Results of meta-analyses.

(2) Cost effectiveness. (i) In considering the relative cost effectiveness of pharmaceutical agents in a therapeutic class, the DoD Pharmacy and Therapeutics Committee shall evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes of the other agents in the class.

(ii) Information considered by the Committee concerning the relative cost effectiveness of pharmaceutical agents may include but is not limited to:

- (A) Cost of the pharmaceutical agent to the Government;
- (B) Impact on overall medical resource utilization and costs;
- (C) Cost-efficacy studies;
- (D) Cost-effectiveness studies;
- (E) Cross-sectional or retrospective economic evaluations;
- (F) Pharmacoeconomic models;
- (G) Patent expiration dates;
- (H) Clinical practice guideline recommendations, and
- (I) Existence of existing or proposed blanket purchase agreements, incentive price agreements, or contracts.

(f) *Evaluation of pharmaceutical agents for determinations regarding inclusion on the uniform formulary.* The DoD Pharmacy and Therapeutics Committee will periodically evaluate or re-evaluate individual pharmaceutical agents and therapeutic classes of pharmaceutical agents for determinations regarding inclusion or continuation on the uniform formulary. Such evaluation or re-evaluation may be prompted by a variety of circumstances including, but not limited to:

- (1) Approval of a new pharmaceutical agent by the U.S. Food and Drug Administration;
- (2) Approval of a new indication for an existing pharmaceutical agent;
- (3) Changes in the clinical use of existing pharmaceutical agents;
- (4) New information concerning the safety, effectiveness or clinical outcomes of existing pharmaceutical agents;
- (5) Price changes;
- (6) Shifts in market share;
- (7) Scheduled review of a therapeutic class; and
- (8) Requests from Pharmacy and Therapeutics Committee members,

military treatment facilities, or other Military Health System officials.

(g) *Administrative procedures for establishing and maintaining the uniform formulary*—(1) *Pharmacy and Therapeutics Committee determinations.* Determinations of the Pharmacy and Therapeutics Committee are by majority vote and recorded in minutes of Committee meetings. The minutes set forth the determinations of the committee regarding the pharmaceutical agents selected for inclusion in the uniform formulary and summarize the reasons for those determinations. For any pharmaceutical agent (including maintenance medications) for which a recommendation is made that the status of the agent be changed from the formulary tier to the non-formulary tier of the uniform formulary, or that the agent requires a pre-authorization, the Committee shall also make a recommendation as to effective date of such change that will not be longer than 180 days from the final decision date but may be less. The minutes will include a record of the number of members voting for and against the Committee's action.

(2) *Beneficiary Advisory Panel.* Comments and recommendations of the Beneficiary Advisory Panel are recorded in minutes of Panel meetings. The minutes set forth the comments and recommendations of the Panel and summarize the reasons for those comments and recommendations. The minutes will include a record of the number of members voting for or against the Panel's comments and recommendations.

(3) *Uniform formulary final decisions.* The Director of the TRICARE Management Activity makes the final DoD decisions regarding the uniform formulary. Those decisions are based on the Director's review of the final determinations of the Pharmacy and Therapeutics Committee and the comments and recommendations of the Beneficiary Advisory Panel. No pharmaceutical agent may be designated as non-formulary on the uniform formulary unless it is preceded by such recommendation by the Pharmacy and Therapeutics Committee. The decisions of the Director of the TRICARE Management Activity are in writing and es-

tablish the effective date(s) of the uniform formulary actions.

(h) *Obtaining pharmacy services under the pharmacy benefits program*—(1) *Points of service.* There are four outpatient pharmacy points of service:

(i) Military Treatment Facilities (MTFs);

(ii) Retail network pharmacies: Those are non-MTF pharmacies that are a part of the network established for TRICARE retail pharmacy services;

(iii) Retail non-network pharmacies: Those are non-MTF pharmacies that are not part of the network established for TRICARE retail pharmacy services, and

(iv) the TRICARE Mail Order Pharmacy (TMOP).

(2) *Availability of formulary pharmaceutical agents*—(i) *General.* Subject to paragraph (h)(2)(ii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all of the points of service identified in paragraph (h)(1) of this section.

(ii) *Availability of formulary pharmaceutical agents at military treatment facilities.* Pharmaceutical agents included on the uniform formulary are available through MTFs, consistent with the scope of health care services offered in such facilities. The Basic Core Formulary (BCF) is a subset of the uniform formulary and is a mandatory component of all MTF pharmacy formularies. The BCF contains the minimum set of pharmaceutical agents that each MTF pharmacy must have on its formulary to support the primary care scope of practice for Primary Care Manager enrollment sites. Additions to individual MTF formularies are determined by local Pharmacy and Therapeutics Committees based on the scope of health care services provided at the respective MTFs. All pharmaceutical agents on the local MTF formulary must be available to all categories of beneficiaries.

(3) *Availability of non-formulary pharmaceutical agents*—(i) *General.* Non-formulary pharmaceutical agents are generally available under the pharmacy benefits program from the retail network pharmacies, retail non-network pharmacies, and the TRICARE Mail

Order Pharmacy (TMOP) at the non-formulary cost-share.

(ii) *Availability of non-formulary pharmaceutical agents at military treatment facilities.* Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through the MTF pharmacies for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent.

(iii) *Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services.* The pharmacy benefits program is required to assure the availability of clinically appropriate pharmaceutical agents to members of the uniformed services, including, where appropriate, agents not included on the uniform formulary. Clinically appropriate pharmaceutical agents will be made available to members of the Uniformed Services, including, where medical necessity has been validated, agents not included on the uniform formulary. MTFs shall establish procedures to evaluate the clinical necessity of prescriptions written for members of the uniformed services for pharmaceutical agents not included on the uniform formulary. If it is determined that the prescription is clinically necessary, the MTF will provide the pharmaceutical agent to the member.

(iv) *Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP.* Eligible beneficiaries will receive non-formulary pharmaceutical agents at the formulary cost-share when medical necessity has been established by the beneficiary and/or his/her provider. The peer review provisions of § 199.15 shall apply to the clinical necessity pre-authorization determinations. TRICARE may require that the time for review be expedited under the pharmacy benefits program.

(i) *Cost-sharing requirements under the pharmacy benefits program—(1) General.* Under 10 U.S.C. 1074g(a)(6), cost-sharing requirements are established in this section for the pharmacy benefits program independent of those established under other provisions of this Part.

Cost-shares under this section partially defray government costs of administering the pharmacy benefits program when collected by the government for prescriptions dispensed through the retail network pharmacies or the TRICARE Mail Order Pharmacy. The higher cost-share paid for prescriptions dispensed by a non-network retail pharmacy is established to encourage the use of the most economical venue to the government. Cost-sharing requirements are based on the classification of a pharmaceutical agent as generic, formulary, or non-formulary, in conjunction with the point of service from which the agent is acquired.

(2) *Cost-sharing amounts.* Active duty members of the uniformed services do not pay cost-shares. For other categories of beneficiaries, cost-sharing amounts are as follows:

(i) For pharmaceutical agents obtained from a military treatment facility, there is no co-payment.

(ii) For pharmaceutical agents obtained from a retail network pharmacy there is a:

(A) \$9.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment per prescription for up to a 30-day supply of a non-formulary pharmaceutical agent.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy there is a 20 percent or \$9.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For non-formulary pharmaceutical agents obtained at a retail non-network pharmacy there is a 20 percent or \$22.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(v) For pharmaceutical agents obtained under the TMOP program there is a:

(A) \$9.00 co-payment per prescription for up to a 90-day supply of a formulary pharmaceutical agent.

(B) \$3.00 co-payment for up to a 90-day supply of a generic pharmaceutical agent.

(C) \$22.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent.

(vi) For TRICARE Prime beneficiaries who obtain prescriptions from retail non-network pharmacies, the enrollment year deductible for outpatient claims is \$300 per individual; \$600 per family; and a point of service cost-share of 50 percent thereafter applies in lieu of the 20 percent co-payment.

(vii) Except as provided in paragraph (h)(2)(viii) of this section, for pharmaceutical agents acquired by TRICARE Standard beneficiaries from retail non-network pharmacies, beneficiaries are subject to the \$150.00 per individual or \$300.00 maximum per family annual fiscal year deductible.

(viii) Under TRICARE Standard, dependents of members of the uniformed services whose pay grade is E-4 or below are subject to the \$50.00 per individual or \$100.00 maximum per family annual fiscal year deductible.

(ix) The TRICARE catastrophic cap limits apply to pharmacy benefits program cost-sharing.

(x) The per prescription co-payments established in this paragraph (i)(2) of this section may be adjusted periodically based on experience with the uniform formulary, changes in economic circumstances, and other appropriate factors. Any such adjustment may be made upon the recommendation of the Pharmacy and Therapeutics Committee and approved by the Assistant Secretary of Defense (Health Affairs). Any such adjusted amount will maintain compliance with the requirements of 10 U.S.C. 1074g(a)(6).

(3) *Special cost-sharing rule when there is a clinical necessity for use of a non-formulary pharmaceutical agent.* (i) When there is a clinical necessity for the use of a non-formulary pharmaceutical agent that is not otherwise excluded as a covered benefit, the pharmaceutical agent will be provided at the same co-payment as a formulary pharmaceutical agent can be obtained.

(ii) A clinical necessity for use of a non-formulary pharmaceutical agent is established when the beneficiary or their provider submits sufficient infor-

mation to show that one or more of the following conditions exist:

(A) The use of formulary pharmaceutical agents is contraindicated;

(B) The patient experiences significant adverse effects from formulary pharmaceutical agents, or the provider shows that the patient is likely to experience significant adverse effects from formulary pharmaceutical agents;

(C) Formulary pharmaceutical agents result in therapeutic failure, or the provider shows that the formulary pharmaceutical agent is likely to result in therapeutic failure;

(D) The patient previously responded to a non-formulary pharmaceutical agent and changing to a formulary pharmaceutical agent would incur unacceptable clinical risk; or

(E) There is no alternative pharmaceutical agent on the formulary.

(iii) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent should be provided to TRICARE for prescriptions submitted to a retail network pharmacy.

(iv) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent should be provided as part of the claims processes for non-formulary pharmaceutical agents obtained through non-network points of service, claims as a result of other health insurance, or any other situations requiring the submission of a manual claim.

(v) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may be provided with the prescription submitted to the TMOP contractor.

(vi) Information to establish clinical necessity for use of a non-formulary pharmaceutical agent may also be provided at a later date, but no later than sixty days from the dispensing date, as an appeal to reduce the non-formulary co-payment to the same co-payment as a formulary drug.

(vii) The process of establishing clinical necessity will not unnecessarily delay the dispensing of a prescription. In situations where clinical necessity cannot be determined in a timely manner, the non-formulary pharmaceutical

agent will be dispensed at the non-formulary co-payment and a refund provided to the beneficiary should clinical necessity be established.

(viii) Peer review and appeal and hearing procedures. All levels of peer review, appeals, and grievances established by the Contractor for internal review shall be exhausted prior to forwarding to TRICARE Management Activity for a formal review. Procedures comparable to those established under §§199.15 and 199.10 of this part shall apply. If it is determined that the prescription is clinically necessary, the pharmaceutical agent will be provided to the beneficiary at the formulary cost-share. TRICARE may require that the time periods for peer review or for appeal and hearing be expedited under the pharmacy benefits program. For purposes of meeting the amount in dispute requirement of §199.10(a)(7), the relevant amount is the difference between the cost shares of a formulary versus non-formulary drug. The amount for each of multiple prescriptions involving the same drug to treat the same medical condition and filled within a 12-month period may be combined to meet the required amount in dispute.

(j) *Use of generic drugs under the pharmacy benefits program.* (1) The designation of a drug as a generic, for the purpose of applying cost-shares at the generic rate, will be determined through the use of standard pharmaceutical references as part of commercial best business practices. Pharmaceutical agents will be designated as generics when listed with an “A” rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the Food and Drug Administration, or any successor to such reference. Generics are multisource products that must contain the same active ingredients, are of the same dosage form, route of administration and are identical in strength or concentration.

(2) The pharmacy benefits program generally requires mandatory substitution of generic drugs listed with an “A” rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA and ge-

neric equivalents of grandfather or Drug Efficacy Study Implementation (DESI) category drugs for brand name drugs. In cases in which there is a clinical justification for a brand name drug in lieu of a generic equivalent, under the standards and procedures of paragraph (h)(3) of this section, the generic substitution policy is waived.

(3) When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate.

(k) *Preauthorization of certain pharmaceutical agents.* (1) Selected pharmaceutical agents may be subject to prior authorization or utilization review requirements to assure medical necessity, clinical appropriateness and/or cost effectiveness.

(2) The Pharmacy and Therapeutics Committee will assess the need to prior authorize a given agent by considering the relative clinical and cost effectiveness of pharmaceutical agents within a therapeutic class. Pharmaceutical agents that require prior authorization will be identified by a majority vote of the Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee will establish the prior authorization criteria for the pharmaceutical agent.

(3) Prescriptions for pharmaceutical agents for which prior authorization criteria are not met will not be cost-shared under the TRICARE pharmacy benefits program.

(4) The Director, TRICARE Management Activity, may issue policies, procedures, instructions, guidelines, standards or criteria to implement this paragraph (k).

(1) *TRICARE Senior Pharmacy Program.* Section 711 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (Public Law 106-398, 114 Stat. 1654A-175) established the TRICARE Senior Pharmacy Program for Medicare eligible beneficiaries effective April 1, 2001. These beneficiaries are required to meet the eligibility criteria as prescribed in

§199.3 of this part. The benefit under the TRICARE Senior Pharmacy Program applies to prescription drugs and medicines provided on or after April 1, 2001.

(m) *Effect of other health insurance.* The double coverage rules of §199.8 of this part are applicable to services provided under the pharmacy benefits program. For this purpose, to the extent they provide a prescription drug benefit, Medicare supplemental insurance plans or Medicare HMO plans are double coverage plans and will be the primary payor. Beneficiaries who elect to use this pharmacy benefits shall provide DoD with other health insurance information.

(n) *Procedures.* The Director, TRICARE Management Activity shall establish procedures for the effective operation of the pharmacy benefits program. Such procedures may include restrictions of the quantity of pharmaceuticals to be included under the benefit, encouragement of the use of generic drugs, implementation of quality assurance and utilization management activities, and other appropriate matters.

(o) *Preemption of State laws.* (1) Pursuant to 10 U.S.C. 1103, the Department of Defense has determined that in the administration of 10 U.S.C. chapter 55, preemption of State and local laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods is necessary to achieve important Federal interests, including but not limited to the assurance of uniform national health programs for military families and the operation of such programs at the lowest possible cost to the Department of Defense, that have a direct and substantial effect on the conduct of military affairs and national security policy of the United States.

(2) Based on the determination set forth in paragraph (o)(1) of this section, any State or local law relating to health insurance, prepaid health plans, or other health care delivery or financing methods is preempted and does not apply in connection with TRICARE pharmacy contracts. Any such law, or regulation pursuant to such law, is without any force or effect, and State or local governments have no legal au-

thority to enforce them in relation to the TRICARE pharmacy contracts. However, the Department of Defense may by contract establish legal obligations on the part of TRICARE contractors to conform with requirements similar or identical to requirements of State or local laws or regulations.

(3) The preemption of State and local laws set forth in paragraph (o)(1) of this section includes State and local laws imposing premium taxes on health or dental insurance carriers or underwriters or other plan managers, or similar taxes on such entities. Such laws are laws relating to health insurance, prepaid health plans, or other health care delivery or financing methods, within the meaning of the statutes identified in paragraph (o)(1) of this section. Preemption, however, does not apply to taxes, fees, or other payments on net income or profit realized by such entities in the conduct of business relating to DoD pharmacy services contracts, if those taxes, fees or other payments are applicable to a broad range of business activity. For purposes of assessing the effect of Federal preemption of State and local taxes and fees in connection with DoD pharmacy services contracts, interpretations shall be consistent with those applicable to the Federal Employees Health Benefits Program under 5 U.S.C. 8909(f).

(p) *General fraud, abuse, and conflict of interest requirements under TRICARE pharmacy benefits program.* All fraud, abuse, and conflict of interest requirements for the basic CHAMPUS program, as set forth in this part 199 (see applicable provisions of §199.9 of this part) are applicable to the TRICARE pharmacy benefits program. Some methods and procedures for implementing and enforcing these requirements may differ from the methods and procedures followed under the basic CHAMPUS program.

[69 FR 17048, Apr. 1, 2004]

§ 199.22 TRICARE Retiree Dental Program (TRDP).

(a) *Purpose.* The TRDP is a premium based indemnity dental insurance coverage program that will be available to retired members of the Uniformed Services, their dependents, and certain other beneficiaries, as specified in